UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

INCYTE CORPORATION
LEGAL DEPARTMENT
3160 PORTER DRIVE
PALO ALTO CALIFORNIA 94304

In re Application of	:
Walker et al	:
Serial No.: 09/996,952	: Decision on Petition
Filing Date: 27 November 2001	:
Attorney Docket No. PB-0016 US	:

This letter is in response to the Petition under 37 CFR 1.181, filed on 23 January 2004, to vacate the final restriction requirement an to require the examiner to search and examine SEQ ID Nos. 1-9. The delay in acting upon this petition is regretted.

BACKGROUND

A review of the file history shows that the Office mailed a 9-way restriction requirement. Applicants elected Group I, claims 1, 2, 3, 9, 10, 11, drawn to a combination comprising a nucleic acid having SEQ ID No. 7, vectors and host cells comprising said nucleic acid, with traverse. Applicants are not traversing the restriction between Group I and Groups II-IX. Instead applicants argue that the restriction requirement for a single sequence within Group I was improper in view of MPEP 803.04.

The Restriction Requirement pertaining to the sequences is set forth below:

> For each of inventions I-IX above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-VI and one of inventions (A)-(P, sic C).
> (A). SEQ ID NO: 4
> (B). SEQ ID NO: 6
> (C). SEQ ID NO: 7.

> It is noted that claim 1, which has been grouped with Group 1, is drawn to a combination comprising a plurality of cDNAs having the nucleic acid sequence of SEQ ID NO: 1-9 and the complements of SEQ ID NO: 1-9. Thus this claim requires that the combination must comprise each of SEQ ID NO: 1-9 as well as the complements of SEQ ID NO: 1-9. This claim is supported by the specification on page Should applicants amend this claim such that it is drawn to a combination comprising a plurality of cDNAS selected from the group consisting of SEQ ID NO: 1-9 and the complements of SEQ ID NO: 1-9, a further restriction will be made between SEQ ID NO: 1-9 and the complements of SEQ ID NO: 1-9.

Applicants elected Group I, SEQ ID NO 7 and traversed the grounds similar to those presented in this petiton. Upon consideration of the traversal, the Examiner stated that:

> Applicants further submit that the Examiner's requirement for applicants to elect a single sequence for examination relative to the claims of Group l is improper and applicants submit that the MPEP 803.04 supports applicants position. Applicants specifically submit that since claim 1 contains less than ten sequences, all sequences of the combination should be examined. Applicants argument is not found persuasive.
> Applicants are reminded that with respect to claim 1 which requires the combination of SEQ ID NOs: 1-9, all of the sequences will be considered/examined. However with respect to the remaining claims, 2, 3, 9, 10 and 11, of Group 1, only SEQ ID NO: 7 the elected Group, will be examined based on the undue burden caused by the search and examination of those sequences claimed in addition to SEQ ID NO: 7, (i.e. SEQ ID NOs: 4 and 6). Applicants are reminded that a complete and proper search of the elected subject matter involves the search of not only the referred to nucleic acid sequences using a number of different multiple databases, but of also the encoded amino sequences using a number of different multiple databases. Further these searches take a considerable amount of time that is dependent on the type and length of the sequences and the various embodiments reasonably considered to be encompassed by "said sequences".

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-8 and 12-20 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b). Claims 2, 3 and 9-11 were rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 and 9-11 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Claims 1-3 and 9-1 1 were rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the enablement requirement.

An amendment and response and this Petition were filed on 12 December 2003.

DISCUSSION

The application, file history and petition have been considered carefully.

Claim 1 reproduced below.

> 1. A combination comprising a plurality of cDNAs having the nucleic acid sequences of SEQ ID NOs:1-9 and the complements of the nucleic acid sequences of SEQ ID NOs:1-9.

The phrase "a combination comprising a plurality of" is being interpreted as meaning that Claim 1 requires more than one copy of each of SEQ ID Nos. 1, 2, 3, 4, 5, 6, 7, 8, and 9. Applicants are correct that Claim 1 is written in the format of MPEP 803.04, Example B, below.

> (B) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000;

If combination claims such as Claim 1, written in the format of Example (B), been the only type filed in this application, they would have been examined as follows:

> Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

The petition argues that the restriction between sequences is not proper in view of section 803.04 of the MPEP. However, MPEP 803.04 states:

> In applications containing all three claims set forth in examples (A)-(C), the Office will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example (A), all combinations, such as in examples (B) and (C), containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed. (Emphasis added).

Fin further support of the restriction requirement, this application does not contain (1) only combination claims as set forth in Example (B), nor does it contain all three claim sets (A), (B) and (C). This application contains additional types of claims that do not conform to the formats of Examples (A), (B) or (C). See Claim 2 reproduced below:

> 2. A cDNA comprising a nucleic acid sequence selected from SEQ ID NOs:4, 6, and 7 and the complements thereof.

Claim 2 is an independent claim written in the format of 3 independent and distinct molecules recited in the alternative. An examination of this claim requires a separate search of each of SEQ ID NO 4, 6 and 7. The search for multiple independent and distinct nucleic acid molecules requires undue burden. Moreover, it is unlikely that applicants would accept prior art found on one sequence being applied to another sequence. However, there is overlap between Claim 1 and Claim 2, as the examiner appropriately recognized. Claim 2 has been properly joined to and examined with claim 1 to the extent that it reads upon the elected sequence. This restriction is proper in view of MPEP 803.04, which states that

> By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

In order to have each of SEQ ID Nos. 1-9 examined together, Applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions. However, if such a petition were filed and granted, any prior art the examiner applies to one sequence may be applied under 35 USC 103(a) as being obvious in view of applicants' admission.

Alternatively, if Applicants were to limit their invention to the combination of claim 1, the restriction requirement would be withdrawn and Claim 1 would be examined as required by MPEP 803.04, Example (B).

DECISION

The petition is **DENIED** for the reasons set forth above.

The application will be forwarded to the Examiner for consideration of the response filed 12 December 2003.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, PO Box 1450, Alexandria VA 22313-1450 or by telephone at (571) 272-1600.

Bruce Kisliuk
TC1600 Group Director